

AD-A264 361

GRANT NO: DAMD17-90-Z-0037

TITLE: INTERNATIONAL FORUM FOR AIDS RESEARCH (IFAR)

S DTIC ELECTE MAY 1 8 1993 C

PRINCIPAL INVESTIGATOR: William Mayer, M.D.

CONTRACTING ORGANIZATION: National Academy of Sciences

Institute of Medicine 2101 Constitution Avenue Washington, DC 20418

REPORT DATE: May 31, 1993

TYPE OF REPORT: Final Proceedings

PREPARED FOR: U.S. Army Medical Research and

Development Command, Fort Detrick Frederick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;

distribution unlimited

The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents.

98 5 17 063

93-10984

31 May 1993 Final Proceedings

International Forum for Aids Research (IFAR)

Grant No. DAMD17-90-2-0037

William Mayer, M.D.

National Academy of Science Institute of Medicine 2101 Constitution Avenue Washington, DC 20418

U.S. Army Medical Research & Development Command Fort Detrick Frederick, Maryland 21702-5012

Approved for public release; distribution unlimited

The International Forum for AIDS Research (IFAR) was a three-year activity established by the Institute of Medicine in January 1990 to enhance coordination of research in prevention and control of HIV/AIDS. The focus of IFAR was "non-biomedical," and member institutions retained complete autonomy and control over their own programs and resources. IFAR was intended to be a flexible entity, offering a neutral forum for ongoing communication, discussion, and problem-solving among funders of AIDS research in developing countries.

The initial IOM proposal called for IFAR to be disbanded or moved to another venue after its three years at the Institute. Current plans call for IFAR to be relocated within, and administered by, the World Health Organization's Global Programme on AIDS and to be chaired by the United Nations Development Programme.

AIDS; Biotechnology; RA I

Unclassified



International Forum for AIDS Research

Institute of Medicine National Academy of Sciences

The International Forum for AIDS Research, "IFAR," was established in January 1990 at the Institute of Medicine, National Academy of Sciences, as a consortium of North American funders of AIDS research in developing countries, particularly in relation to prevention and control, epidemiology, operations, and building human and institutional capacity.

The concept of the Forum emerged from a series of meetings in 1988-89 among administrators and scientists working in international public health, who noted two imperatives: a need to increase the flow of financial resources to epidemiologic and applied research in developing countries, especially in Africa but not necessarily limited to that continent; and a need to assure that those resources be allocated with optimum effectiveness. The founding group concluded that real utility might be found in a forum mechanism that could contribute to coordination of certain kinds of research related to the AIDS epidemic, as well as the corresponding funding. The charge to IFAR was to:

- Create and maintain a network of institutional linkages and information exchange among concerned funding agencies, investigators, and interested governments
- Foster sustained dialogue aimed at guiding the international applied research agenda toward greater coherence, complementarity, and productivity
- Marshall support for high-priority collaborative activities, including long-term institutionbuilding efforts and multidisciplinary endeavors.

The group also set some ground rules for the forum. Its focus would be "non-biomedical." Its membership would, at least initially, consist of North American funders and researchers, but be open to others. Member institutions would retain total autonomy and control of their own programs and resources. Meetings would be

held regularly, three to four times each year, with a prominent place reserved at each for developing country institutions and research leaders. The IFAR would maintain a close and steady relationship with the WHO Global Programme on AIDS, with whose activities it would be explicitly complementary. And, in keeping with customary practices of the Institute of Medicine, an independent committee (now constituted as the Scientific and Technical Advisory Committee, "STAC") would serve as a resource for the forum, in network formation, information gathering and dissemination, special workshops, and publication.

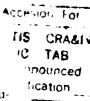
IFAR is not, in itself, a funding agency. It has a small professional and administrative staff, and is intended as a flexible entity which offers a place and a focus for ongoing communication, discussion, diffusion, and problem-solving among funders, researchers, and concerned health professionals. It is not designed to supplant or replace existing institutions, and strives to avoid duplication or competition with projects and networks already well established. Finally, it is still evolving; its precise directions and attentions are formulated in an iterative process by its participants and the activity is continuously evaluated to determine its utility.

Priority Issues

In May 1990, in its first meeting as a formally constituted body, the Forum agreed on the following as matters of concern meriting priority attention by researchers and funders:

1. Training personnel in developing countries where AIDS is a public health concern, and the integration of training with capacity building

2. Collaboration with developing world institutions and personnel in shaping research agendas



Distribution /

Availability

Dist Avail and Special S

- 3. Associations between the sexually transmitted diseases and the HIV infections
 - 4. Impact of AIDS on maternal and child health
 - 5. Social and economic impact of the AIDS pandemic on developing countries
 - Planning and ethical considerations associated with preparations for drug and vaccine trials
 - 7. Role of social and behavioral research in formulating intervention strategies
 - 8. Associations among condom distribution, preventive education, and HIV transmission
 - Evaluation of research, education, and intervention programs
- Community-based treatment and education programs
- 11. Relationship between HIV/AIDS, tuberculosis, and tropical diseases
- Integration of AIDS activities with other primary health care activities.

First Priority: Development of Capacity

In its first meeting, the Forum's Scientific and Technical Advisory Committee pursued the first priority. It agreed that capacity development is proving persistent and fundamental, and will matter increasingly as clinical trials and interventions go into place. Important dimensions are:

- A mounting need for information sharing among funders
- Plans and strategies that are long term in nature
- Adequate time for planning and preparation for drug and vaccine trials
- Training: terms, location, skills, continuance/ reinforcement, trainee identification, "depth," and variety
- Integration of capacity building into applied research, programmatically and financially
- Incentives, disincentives, and the decisionmaking process
- Monitoring, evaluation, and follow-up.

The Committee suggested that the Forum conceive of its next meeting as a workshop on the subject of "training" and convene presenters, to include IFAR members

but emphasize non-members, who would describe: essential outlines and ingredients of their organizations' education and training programs; program outputs, expressed in numbers of trainees and their current placement status; evaluation processes; and learning about strengths and weaknesses. The group discussion would be a provocative but collegial dialogue. It would emphasize lessons learned and, optimally, arrive at consideration of opportunities for expansion, integration, or joint undertakings with other programs, and take first steps toward resolution of dilemmas perceived as shared.

IFAR Workshop: International Training Programs

On October 31, the IFAR convened for the second time around two interrelated "looking-glass" themes. IFAR Director William Mayer set forth the first theme, "Searching Our Souls about the Role of International Training Programs," which was followed by presentations by:

Robert Fischer: ICARs at NIAID

Helene Gayle: CDC Pilot Training Program

Kenneth Bridbord: Fogarty Training Program

Jeffrey Harris: AID Training Programs

Pat Trites: Training through the International Development Research Centre

Alan Ronald and Joanne Embree: University of Manitoba, Training for the Kenya Project.

The afternoon panel, moderated by Samuel Thier, President of the Institute of Medicine, launched the second theme, "Strengths and Weaknesses of International Training Programs: How Much Do They Contribute to Capacity Building?" The panel members were:

lames Chin, WHO/GPA

Alexandra Jones, International Health Policy Program

Douglas Klaucke, CDC/Global Epidemic Intelligence Service

Charles Carpenter, Brown University, International Health Institute

Jose Barzelatto, Ford Foundation

Scott Halstead, Rockefeller Foundation/INCLEN.

To oversimplify a complex discussion, the day's dialogue took place essentially at two levels, one more practical, one more philosophical. The first queries dealt with matters of efficiency and, in a fairly restrictive sense, effectiveness: where, whom, and what to train; what

support structures must be contemplated; how training given country, and are aimed at gathering knowledge to investments are monitored and protected. This level of discussion generated such questions as: can in-country training curricula be as complete as those provided in sponsor-country institutions? Are the appropriate trainers and collegial networks available in country? Are facilities adequate for training and research? Is sponsorcountry training really adaptive for developing-country technologic and institutional contexts? Does it encourage "brain drain" when trainees from developing countries elect not to return to their home countries?

•

The bridge to larger questions, which really have to do with development and research philosophy, was the question of time and, correspondingly, money, expressed in the willingness and abilities of funder and host countries to sustain longer-term commitment toward the creation of critical mass. As it moved to this different plane of inquiry, the group concluded that there were several logically prior sets of competing concepts that must be sorted out before strategies can be designed to increase research capacity and identify what part training should play in those strategies.

Examples of such competing, but not mutually exclusive concepts include:

- National Priorities vs **Global Priorities**
- Capacity-building vs. Scientific Data Production
- Institutional Development vs. Personnel Development
- Longer-term Programs vs. **Shorter-term Projects**
- In-country Programs vs. Sponsor-country Programs.

Each set of often-opposed purposes cascades to the next and raises questions which should be addressed at the outset, if programs are to be clear about what they are trying to do, if cost-effectiveness is to be calculated truly, and if there can be any real integration among programs.

For instance, the first of the competing concepts asks for clarity about whom the research is meant to benefit. Global precedences stem from crisis situations, and actions that address the crisis call for immediate implementation and require shorter-term plans. Programs focused on global needs are often temporary within a

clarify an acute problem. Locations and target populations for research are selected on the basis of how easily and quickly research findings can be obtained.

National priorities are focused on the needs of the country's citizens and are usually viewed in the overall framework of the country's development. The activities are sustained and reflect local needs in the program bias. While the two agendas are not mutually exclusive and there are almost always areas of overlap, they nonetheless generate real tensions, within and across national and international institutions. For example:

- · How can acute global needs that are geared toward immediate findings be addressed without ignoring or imperiling specific and longerterm national priorities?
- How important is it for U.S. organizations to be concerned with capacity building, especially if the program mandate is focused on wientific findings? Is capacity building or institutionstrengthening important because it is effective in terms of program implementation and cost, or is it important because of its ethical implications? What are the responsibilities of the host and sponsor countries to each other? What is gained by the host and sponsor countries? How can they benefit each other?
- How should scarce resources be distributed? Should all or most of the funds be spent on personnel training and development? Is it equally important to invest in laboratory equipment, supplies, and/or office space, to ensure that trained personnel have the adequate infrastructure in which to utilize their training?
- What are the cost and ethical considerations in implementing in-country or sponsor-country training? Is there an ideal combination?

The group concluded that tensions of this nature are real and some can only be resolved with difficulty, if at all. At the same time, there was concurrence that a thoughtful listing or "mapping" of what is going on in training and/or capacity development would, at a minimum, make it possible for funders and researchers to discuss their plans and purposes. In so doing, they could at least try to account for what might become crosspurposes, as early in the development process as possible. The bottom line from this preliminary exploration is that hard, conjoint analysis of capacity development is just beginning, must go further, and shall be a continuous theme for the IFAR throughout its discourse.

International Forum for AIDS Research Membership

Agency for International Development Jeffrey Harris, MD Bradshaw Langmaid William H. Lyerly, Jr., MS

American Foundation for AIDS Research Mervyn Silverman, MD Trish Halleron, MPH

<u>Centers for Disease Control</u> Helene Gayle, MD, MPH

Ford Foundation Christina Cueva, MA

International Development Research Centre Richard Wilson, MD Pat Trites, MA

National Institutes of Health
Kenneth Bridbord, MD
Alastair Clayton, MB, ChB, FRCP (C)
Karl A. Western, MD, DTPH

The Panos Institute
Donald Edwards, MPH, MSN

Rockefeller Foundation Soth Berkley, MD Scott Halstead, MD

<u>United Nations Development Programme</u> Timothy S. Rothermel, JD

US Public Health Service Ronald St. John, MD

Walter Reed Army Institute of Research Colonel Donald Burke, MD Beth L.P. Ungar, MD

World Bank Mead Over, PhD Rodolfo Bulatao, PhD

World Health Organization
David Heymann, MD
A.D. Brandling-Bennet, MD
Mercedes Weissenbacher, MD, PhD

Scientific and Technical Advisory Committee

Lincoln Chio-ho Chen, MD, MPH (Chair) Harvard University

Charles C. J. Carpenter, MD Brown University

R. Gordon Douglas, Jr., MD Merck Sharp & Dohme International

Douglas Feldman, PhD University of Miami

Donald Henderson, MD, MPH The Johns Hopkins University

Donald R. Hopkins, MD, MPH Global 2000 Inc. Carter Presidential Center

Adetokunbo O. Lucas, MD, DPH Harvard University

Alan Ronald, MD University of Manitoba

Catherine Wilfert, MD
Duke University School of Medicine

STAC Liaison: Judith Wasserheit, MD, MPH, Sexually Transmitted Diseases Branch NIAD/NIH

The International Forum for AIDS Research is located within the Division of International Health, Institute of Medicine, National Academy of Sciences

2101 Constitution Avenue, N.W. Washington, DC 20418 Tel: (202) 334-2348 Fax: (202) 334-3861

Direct Inquiries to: William Mayer, MD, Director Lita Curtis, MPH, Associate Director



International Forum for AIDS Research

Institute of Medicine National Academy of Sciences

INTERNATIONAL AIDS VACCINE TRIALS

The fact that promising AIDS vaccines may emerge in the next few years offers the international medical and public health community a unique challenge. Can international vaccine trials, with all their managerial, ethical, and cultural implications, be planned and carried out on an expedient timetable? The necessary preparatory steps toward the successful management of such trials is the subject of new international concern.

Why International Trials?

The rationale for testing the efficacy of an AIDS vaccine in both the developing and the developed worlds is at least twofold. First, the developing world has the greatest volume of HIV infection, and therefore a large candidate pool for the tests. Second, developing nations are interested in an HIV vaccine, not only for its preventive possibilities, but also in the hope that it will provide immunotherapy, since existing anti-viral drugs are prohibitively expensive.

International trials, however, pose a number of problems. First, the range in the genetic strains of the virus and its capacity for mutation suggest it may be difficult to produce a vaccine that is effective in all settings. A vaccine effective in North America may not work in other regions. This prospect poses difficult questions for North American and European research institutions. Must they work on several vaccines at one time? A global health perspective suggests the pandemic cannot be controlled in one area and left unchecked in another, particularly in a time of rapid global travel and massive human migration.

Second, successful trials will require international collaboration at all levels. These include the need for consensus on ethical issues, on procedures, on logistics and on what care, if any, those individuals who participate will receive.

Finally, infrastructural constraints to setting up the trials include those of site selection, site preparation, and

capacity building of the system that will carry out the trials. The problem will be to avoid what has been termed "safari research," or "medical imperialism" while gathering the necessary data. A further problem concerns how Western researchers will collaborate with Third World researchers, at a how international vaccine trials will leave Third World research establishments enriched.

Progress Towards a Vaccine

Although the IFAR meeting was not intended to debate the scientific merits of the various vaccines in development, <u>Dr. Mary Lou Clements</u> of Johns Hopkins University described several promising candidates. These vaccines are being tested in HIV sero-negative populations that have never been infected with the virus, and also in sero-positive individuals as a post-infection immunization or immunotherapy.

Dr. Clements reminded the participants of the three phases of vaccine trials. Phase I trials are designed to determine the safety of the vaccine, measure the extent of adverse reactions, and develop a preliminary idea of dose. Phase II trials presume upon evidence in animal model systems that the vaccines are safe and could actually protect against infection, and determine optimal dose for safety and immunogenicity. Phase III trials de-

IFAR Conference Summary

The International Forum for AIDS Research (IFAR) focused upon the "Preparation for International Vaccine Trials and Their Management" in its third international meeting, February 12-13, 1991, in Washington, DC. The meeting was launched by Dr. Samuel Thier, President of the Institute of Medicine and chaired by Dr. William Mayer, IFAR Director.

This article is a descriptive summary of that meeting and has not been submitted to standard NAS/IOM review processes. The comments are those of the participants.

termine the efficacy of the candidate vaccine in providing protection. They are placebo controlled, randomized, and double blinded, with sample size based on the incidence of infection.

Dr. Clements urged that developing countries be involved earlier in the testing process than Phase III trials. This would permit them to better assess the safety of the candidate vaccines for their populations and account for different levels of immune response.

She cautioned that clear counselling on the possible consequences to study subjects was essential, since individuals who have a successful immunization will develop antibodies that might test positive in screening tests widely used for travellers, in blood banks, and by employers and the military. Documentation that the subjects had received the vaccine and/or participated in the trial must be provided to those subjects, in addition to very careful counselling that would fully educate potential subjects about risks. She also expressed hope that a better test would be developed that could distinguish between antibody induced by infection as opposed to antibody induced by immunization.

Ethical and Legal Aspects

Dr. Ronald St. John of the U.S. Public Health Service presented the preliminary guidelines from the Consultation on International Collaborative HIV Research that took place in Annapolis, Maryland, in September, 1990. Based on the international standards set forth in the Declaration of Helsinki, the Nuremburg Code, and the guidelines set forth by the World Health Organization and the Council for International Organizations of Medical Sciences (CIOMS), the initial guidelines affirm that research which cannot ethically be performed in the U.S. cannot be performed by U.S. agencies or organizations internationally. This must be recognized despite mounting pressure on governments and scientific investigators to find quick and effective solutions, and general impatience for results.

Institutional Agendas and Leadership

Dr. David Heymann of WHO reported on a November meeting in Geneva on preliminary criteria for selection of sites for vaccine efficacy trials. These fall into four categories: epidemiologic (incidence and continuous onsite collection of virus to determine antigenic variation); clinical and laboratory capability (for high visit volumes, monitoring safety and toxicity, and measuring endpoints); logistical/operational (training and infrastructural capacity); and ethical (assured confidentiality, preand post-screening counselling, and prevention guidance). He noted the difficulty some countries would have in responding to these criteria, and the importance of starting to develop that responsiveness now. WHO

has begun selection of six to seven institutions or centers to support Phase III efficacy trials in the identified countries. The process includes discussion with concerned institutions in developed countries; preliminary assessment team visits; elaboration of strengthening plans, including training; and actual site development, with a two-year target date for completion.

A WHO Vaccine Development steering committee will decide WHO's exact role in the trials and develop criteria for vaccine admission to sites. These will be submitted for international consensus and can serve not only WHO sites but, possibly, other trial sites. The WHO is also studying potentials for a perinatal vaccine, updating 1982 International Guidelines for Biomedical Research, drafting epidemiologic and drug/vaccine trial guidelines, and devising an ethical criteria checklist for researchers.

Dr. Daniel Hoth of the National Institutes of Health urged IFAR participants and other individuals interested in vaccine trials to begin to plan immediately, since efficacy trials will be warranted within the next two to five years. He reiterated the need for less developed countries to be involved in Phase I trials, since safety and efficacy may vary in different populations. This would mean that trial implementation should not move in traditional linear fashion, but would proceed along parallel lines.

He also said there would be multiple trials because there are multiple populations, and that we should assume that there will be multiple HIV vaccines. He warned that risk-benefit tolerance could vary among countries and among settings, so that old standards for risk-benefit assessment would have to be reviewed for a new vision of what is acceptable. He stressed that a great deal of coordination among organizations and disciplines win be needed, since there are so many factors involved in the disease, and because no organization can do it all.

Dr. Peter West of the U.S. State Department talked about the U.S. commitment to ensuring effective collaboration among U.S. agencies conducting or supporting international Hrv trials, and the possible danger of the trials' use for propaganda or disinformation about U.S. involvement. The State Department's special role is being alert to ways in which the ethical and logistical complexities of interntaional trials can generate diplomatic complexities.

Perspectives from Africa

Dr. Gabriel Ogunmola, University of Ibadan, Nigeria, made three particularly relevant points. The first cited glutathione deficiency in African populations in malarious areas as a putative risk factor, suggesting another possibility of antigenic variation. The second raised insti-

tution-building as crucial to trials. New diagnostic laboratories in Nigeria devoted to the molecular biology of HIV are one dimension of this, establishment of collaborative scientific teams in African research centers another Finally, Dr. Ogunmola raised the dilemma of post-trial vaccine accessibility and drew an analogy to subsidies for contraceptives for developing countries.

Issues of Implementation

Dr. Jonathan Mann of Harvard University led a lively open discussion debating the role of WHO in HIV vaccine trials. Dr. Mann maintained that WHO was indispensable to the process and called for a proactive role for the organization. He felt that the trial sites were essential world resources, and should be protected. Concerned about the inequality between partner nations, Dr. Mann reminded sponsor organizations that true collaboration was difficult to achieve when the financial resource base was so heavily weighted toward one national partner. Balanced veto power and a common framework for resolving differences could best be brokered through the proactive offices of the WHO. The limitations of WHO's role in hands-on implementation were explored collectively by the group.

Dr. Mann followed up the issue of accessibility raised carlier by Dr. Ogunmola. All participants were concerned with the ethics of conducting trials without a clear plan and commitment to make a subsequent vaccine available to populations beyond the trial participants. To address the issue of the cost implications of expanded availability of vaccines, Dr. Mann suggested an extension on another profitable patent held by a particular pharmaceutical company in compensation for the costs of HIV vaccine development. Another possibility mentioned was some kind of "superfund." The participants felt the issue of accessibility was serious and complicated enough to warrant at least a follow-up subcommittee meeting, and perhaps a later IFAR meeting

Dr. Anke Ehrhardt from the Columbia University HIV Center, said that social scientists should be involved in each stage of introducing and conducting trials in any community. She pointed to the importance of the "prephase," during which trust is established and researchers learn about variables that will affect their work, for example, immunization practices, language, and stigma. She asserted that only through thoughtful motivation, participatory education, persistent feedback, and followup can adequate compliance occur and risk behavior be accurately assessed. Trials and associated counselling require multi-disciplinary approaches engaging basic scientists, clinicians, social and behavioral scientists, hostcountry counterparts, and pivotal local leaders. Finally, counselling for reduction of risk behavior must be presented in ways that are understandable, by individuals

who are trusted, and in ways that will motivate volunteers for the study.

In Conclusion

The meeting was concluded by two working group sessions and presentations. One of the sessions focused on strategies for incorporating a behavioral/social science component in international vaccine trials, and was facilitated by <u>Dr. Anke Ehrhardt</u> of Columbia University and <u>Dr. Polly F. Harrison</u> of the Institute of Medicine. The group discussed how knowledge, attitudes, and beliefs affect trials; the identification and recruitment of populations; and risk behavior and compliance issues, from entry to exit.

The other working session discussed strategies for the planning and administration of efficacy trials, and was facilitated by Dr. Robert Black of Johns Hopkins University and Dr. Robin Weiss of the Institute of Medicine. The points emphasized by the working group included the need for establishment of a global community of scientists, health professionals, and ethicists, to set the bases for the selection of Phase III vaccines. The information on which selections are based should be drawn from Phase I and Phase II trials in animal models and human volunteers. The group also noted the importance of resisting the pressure to test the first vaccine candidate available. Full participation of developing country scientists was said to be critical, with implementation of trials based on population studies. The issues of cost and accessibility to the general population were of serious concern to the working group, as they were in the overall general discussions.

Suggested Further Reading

Begg, Norman and Elizabeth Miller, "Role of Epidemiology in Vaccine Policy," <u>Vaccine</u>, Vol. 8, June 1990, pp. 180-189.

Matthews, Thomas J. and Dani P. Bolognesi, "AIDS Vaccines," <u>Scientific American</u>, October 1988, pp. 120-127.

Ellerbeck, Edward and Mary Lou Clements, "AIDS Vaccines," <u>Principles and Practices of Infectious Diseases</u>, Update 7, Merck Sharp & Dohme, 1990.

"Human Trials Under Way for AIDS Vaccines," <u>The</u>
<u>Double Helix</u>, National Foundation for Infectious
Diseases, October 1990.

Koff, Wayne, "HIV Vaccine Development: Current Status and Future Directions," Institute of Medicine, Workshop on HIV Vaccine Development Research, January 22, 1990.

Koff, Wayne and Daniel F. Hoth, "Development and Testing of AIDS Vaccines," <u>Science</u>, Vol. 241, July 22, 1988, pp. 426-432.

"Summary of the HIV Vaccine Development Research Workshop," Institute of Medicine, January 22, 1990.

International Forum for AIDS Research Conference on

"Preparation for International Vaccine Trials and Their Management"

Permanent IFAR Members

Agency for International Development

Robert Bernstein Jeffrey Harris Bradshaw Langmaid William Lyerly, Jr.

American Foundation for AIDS Research

Mervyn Silverman Patricia Halleron

Centers for Disease Control

Helene Gayle
Ford Foundation
Christina Cuevas

International Development Research Centre/Canada

Pat Trites

National Institutes of Health

Kenneth Bridbord Alastair Clayton Linda Reck Karl Western Panos Institute

Don Edwards

Rockefeller Foundation

Scott Halstead Seth Berkley

United Nations Development Programme

Timothy Rothermel U.S. Public Health Service

Ronald St. John

Walter Reed Army Institute of Research

Donald Burke Beth Ungar <u>World Bank</u> Mead Over Randy Bulatao

World Health Organization

David Heymann A.D. Brandling-Bennet Mercedes Weissenbacher

Members of the Scientific Technical Advisory Committee (IFAR)

Lincoln Chen, Harvard School of Public Health
Charles C. J. Carpenter, Brown University
R. Gordon Douglas, Merck Sharp and Dohme International
Douglas Feldman, University of Miami
Donald Henderson, Johns Hopkins University
Donald R. Hopkins, Carter Presidential Center
Adetokumbo O. Lucas, Harvard University
Alan Ronald, University of Manitoba
Catherine Wilfert, Duke University School of Medicine
Judith Wasserheit, NIAD/NIH (Liaison)



Other Participants and Speakers

Donna Blair, U.S. Department of State
Wendy Cook, United Nations Development Programme
Robert Fischer, National Institutes of Health
Talmira Hill, Johns Hopkins University
Anne Marie Kimball, Pan American Health Organization
Wayne Koff, National Institutes of Health
Dale Lawrence, National Institutes of Health
Norman Miller, Dartmouth Medical School
Armando Peruga, Pan American Health Organization
Lane Porter, Private Health Law Practice
Frederick Robbins, Case Western University
Eleanor Savage, U.S. Department of State
Basil Vareldzis, Whitman Walker Clinic
Fernando Zacarias, Pan American Health Organization

The International Forum for AIDS Research is located within the Division of International Health, Institute of Medicine, National Academy of Sciences

2101 Constitution Avenue, N.W. Washington, DC 20418

Tel: (202) 334-2348 Fax: (202) 334-3861

Direct Inquiries to: William Mayer, MD, Director Lita Curtis, MPH, Assoc. Dir.



International Forum for AIDS Research

Institute of Medicine National Academy of Sciences

Behavioral Interventions for the Prevention of Sexual Transmission of HIV

Behavioral interventions for the prevention of sexual transmission of HIV infections, although frequently discussed and advocated, are little understood. For some, they are crucial for the present and for the foreseeable toture because they are the only strategy at hand until tested preventive and curative therapies become readily available. For others, the concept is too nebulous and clusive to open analize or assess. And for many, the changing of human behavior in any durable, consistent way is simply impossible. A further impediment to understanding behavioral interventions is the rich diversity. or disciplines involved, each with its own language and distinctive approach. The net effect is some considerable confusion, not a little skepticism, and what amounts to a schism between the biomedical and social scientific communities. While that schism is not new, it is, in the case of the HIV infections, particularly improductive.

The fourth meeting of the International Forum for AID's Research was organized around three overall objectives, a) to consider a model for categorizing behavioral interventions; b) to share information about current behavioral intervention programs in which IFAR members are involved; and c) to foster discussion about the adequacy of present strategies. The meeting began with an analytical phase that explored aspects of methodology, followed with presentations on selected programs, and concluded with a generic case study exercise that highlighted different social scientific perspectives on producing change in human behavior.

PART I: Classifying Behavioral Interventions

Although there are numerous ways to classify behavioral interventions, one useful way is to begin with the people for whom the interventions are intended. Does the intervention intend to change the behavior of a single individual, for example, a newly diagnosed HIV positive case, a partner of an infected person, or an adolescent at risk? Or, does the intervention address some

cohort of individuals, for instance, an entire village or group at special risk, such as truckers or sex workers? Or, finally, is the intervention meant to cut across communities, touching individuals and risk groups alike with print or electronic messages?

Drs. Laurie Liskin, Lawrence Kincaid and Phyllis Protrow of the Center for Communication Services, the Johns Hopkins School of School of Hygiene and Publis Health, led a session illustrating each of these categories.

Strategies Targeted to the Individual

"AIDS prevention counselling" covers a broad racge of strategies whose dedicated target is the individual counselling by peers, and provider-client interaction in clinic-, community-, or home-based care environment-Experience with family planning programs worldwide is that provider-client interaction, particularly in clinic settings, offers considerable potential for motivating individual behavioral change. That potential has not been realized in connection with prevention of HIV intections for a number of reasons, examined for the IFAR group by Dr. Laurie Liskin.

Major problems in AIDS prevention counselling, encountered in Africa but probably not exclusive to that continent, include the following phenomena: 1) counselling is rarely part of the health worker-patient relationship, primarily oriented toward curative care; 2) fear of patient suicide or vengeful behavior; 3) no support services locally available which could justify sharing a positive diagnosis with a patient; 4) lack of information and training on the part of health workers; and 5) great stigma.

Nonetheless, prevention counselling is essential and opportunities are being missed. Dr. i iskin provided a case example from Zambia, where the Ministry of Health asked for help in developing materials for

training AIDS counselors. Video was selected as the most effective and dramatic medium. The film's objectives were established collaboratively with indigenous counselors and trainers. The prime objectives illustrate: a) typical and difficult counselling situations, b) the emotional issues surrounding HIV diagnosis, and techniques for facilitating an environment where clients could make healthy decisions. Perhaps the most crucial lessons learned were that: counselling must go beyond information-giving or persuasion; budgets must allow for more that one counselor to account for burnout; administrative support is essential, particularly in terms of adequate time scheduled into work routines and space allotted to conduct sessions; and counselling should be institutionalized as a clearly defined job specialty with its own defined career track, incentives, and role redefinition.

As for the impact of counselling, while there is good evidence for its effectiveness in family planning programs, AIDS prevention counselling as practiced now is not a quick or easy route to behavior change, either through increasing condom use or through reducing number of partners. While there is evidence of greater condom use in couple relationships, there has not been comparable behavior change outside the couples. A major dilemma is that most individuals currently do not encounter counselling until they enter the health care system because one of the partners is symptomatic. However, although not enough research has been done on the long-term impact of AIDS counselling, there are good lessons from family planning that show that even one good counselling session can make a difference in sexual practices.

Strategies Targeted to the Community

Dr. Lawrence Kincaid spoke of several alternative ways of organizing behavioral change interventions at the community level - mass media, use of local organizations, and building on identified community networks. A variant of the last approach derives from a strategy used in Bangladeshi family planning outreach programs. The central assumption is that individuals cannot easily change their behavior in isolation. However, they are more likely to do so when there is a critical local mass of influence supporting change. In the approach described by Dr. Kincaid, communication and friendship social network data are collected and mapped. The goals are to locate the community opinion leaders and individuals with a high number of sexual contacts. Computer simulations are then performed to predict what would happen using various network intervention strategies. The theory guiding these strategies is that it is the "persuasability" of the person attempting to influence change, multiplied by the frequency of communication, divided by the square of the distance from the intended "influencer" in the total communication/

sexual relations network, that is most likely to produce behavior change.

Preliminary findings, from this study and from an intervention in a North American urban context, are that an intervention using a selection of 10% of the most central nodes in a network produces a "success rate" of about 90%; 5% produces a rate of 71-83%. The broader findings of the study reinforce the findings encountered in the work described by Dr. Liskin first, that information alone is not enough and, second, that a support structure is essential for potentially efficacious and durable intervention.

Strategies Targeted Across Communities

According to Dr. Piotrow, the mass media are assuming a new role in health promotion that has not been fully conceptualized, understood, researched, or evaluated. She suggested that AIDS might even be called "the first mass media disease" since more people get information on AIDS from the media than they do from their own health care providers or the health service system. The younger generation, the cohort with the highest contal frequencies, is the first generation to grow up exposed to such a tremendous amount of mass media, particularly electronic media. There is one radio for every two people and one television for every twelve people in the developing world to lay; sales of television sets worldwide have tripled in the last six years.

The mass media convey information, set agendas, legitimate discussion on issues, and play a role in creating community norms. The average married couple spends two to three hours per day watching television, but only fifteen minutes per week in interpersonal conversation about important issues.

The most controversial aspect of mass media is the question of whether they can actually change behavior. Dr. Piotrow contends that, carefully designed and presented in an entertainment format linked to specific service providers or programs, mass media messages will stimulate various types of behavior change. The first type is simply information seeking, when a member of an audience becomes curious about something seen or heard through some mass medium. The second occurs when a message or issue presented through mass media prompts a high degree of communication within social networks, for instance, spouses, parents and children, or communities. This increased communication is a behavior change in itself and can be seen as an intermediate step that may lead to initiation and continuation of new behavior.

Dr. Piotrow summarized the reasons why mass media, especially entertainment formats, can change behavior, using a formula she called "the six P's." The "enter-

educate" approach is popular; people like it. It is pervasive, that is, easily accessible. It can be passionate, that is, it has emotional impact on the audience, especially important since behavior change is driven more by emotion than rationality. It is personal, allowing the audience to identify with the entertainers perhaps more easily than with their own interpersonal relations and, because it presents both good and bad role models who may change their own behavior, entertainment can be persuasive. Finally, media entertainment is profitable, able to pay for itself at least to some degree.

Dr. Piotrow concluded with evidence from Ghana and Brazil that positive mass media messages seem to work better than those that are negative. She cited the successful vasectomy campaign in Brazil that featured dancing hearts proclaiming vasectomy as an act of love, since the men who had them loved their wives enough to protect them. A 285% increase in vasectomy requests was recorded at the specific clinic that was advertised in the campaign. The point becomes one of making individuals feel good about what they ought to be doing, rather than bad about doing the wrong thing

Evaluation of Mass Media Campaigns

Dr. Jonathan Baggaley of Concordia University, Montreal, presented a lively example of the difficulties of evaluating mass media: a video film made through Street Kids International's campaigns on four continents. In the Dominican Republic, the evaluation quickly evolved from the simple question of whether it was effective, to a community development process in which

the video spurred the production of various companion products for education. This led to the conclusion that all mass media products should be evaluated within some kind of community development process. As in the work described by Dr. Kincaid, the importance of working through "gate-keepers" became quickly apparent: in the Caribbean case, str. i workers would not allow the evaluation of a media education product that was not performed through them. This required training the street workers and institutionalizing the training and evaluation processes.

Dr. Baggaley concluded that traditional, more conventional methods of evaluation are the least reliable in the context of AIDS preventive interventions. He advocated that such approaches be combined with more innovative electronic methods like those used in contemporary political and commercial campaigns.

PART II: Human Sexuality: Exploring and Analyzing Social Science Approaches to a Country Case

A country case study, developed by Dr. Norman Miller from Dartmouth Medical School and Ms. Lita Curtis from the Institute of Medicine, was based on a composite of African countries. The case, duly named "Africana," was presented as a means of fostering discussion of how different social science approaches might be applied to the design of research and program interventions. The scholarly approaches were then weighed against presentations on the political and legislative realities that surround the AIDS issue. (See case highlights below.)

"Africana" Highlights

- Four of the 20 ethnic groups predominate. The President is from a minority group. Policy is made by five of the President's advisors. No women have access to this top echelon.
- The research climate has become restrictive and the epidemic is not publicized for fear of urban unrest and loss of tourism.
- It is one of the 12 most seriously infected countries, with the largest percentage of infection found in urban areas. Seroprevalence is about 14%, growing by about 2% a year. HIV transmission rates are high in eight of the 20 ethnic groups.
- Male circumcision is at 60% and female circumcision rates are unknown. A government campaign against female circumcision has had little follow-up or evaluation.
- Average age of first sexual intercourse is 14 for males and 15 for females. Marriage is often conditioned on pregnancy as guarantee of female fertility. Women desire 8.6 children.
- Extramarital sex is widely practiced by men; more hidden in women, but occurs frequently when husbands migrate to cities. Polygamy is practiced by 20% of the population
- Most women have little education and few vocational skills. Widows have few options is support themselves. The second largest ethnic group follows the practice of marrying widows to the dead husband's brother, regardless of the cause of death.
- There are six military bases; three ground, two air, and one naval; where seroprevalence is 24-31%. The main road has many truck stops served by hotels and brothels.

Demographic Profile

The demographic data used in creating Africana was based on an application of a model developed through the inter-agency working group of the U.S. State Department, and supported by the AIDS Division of the Agency for International Development. (See infold in <u>AIDS & Society</u>, Vol. 2 No. 3, April/May 1991.)

Dr. Peter Way from the U.S. Census Bureau presented the baseline demographic profile. The central questions that he posed in terms of the results were:

- What kinds of timing would be most effective in reducing an epidemic in one area or another?
- What kinds of groups in the context of geographic distribution are best to focus on?
- What ages might be most affected?
- What are the processes that are contributing to the epidemic?

Anthropology

Dr. Carl Kendall from the Johns Hopkins University presented an anthropologic perspective on interventions. He noted that in this case, AIDS is primarily an urban disease, but he pointed out that the impact of urbanism extends into rural areas too. He also observed that anthropologists were not welcome in the case country due to past research focus on customs that were considered barbaric in the west.

The first tool to utilize in the intervention design was to focus on the cultural diversity that continues to exist even after people move from rural areas to the city. He recommended utilizing kin and ethnic networks that attract and help prepare migrants for urban life by training key individuals within them to counsel new arrivals on safer sex practices.

He emphasized that both positive and negative sanctions within the network were important, and that women particularly should be trained as educators. He cautioned against stigmatizing populations or ethnic groups in the process of targeting them for interventions.

Community leaders are natural magnets for migrants, so a short-term intervention might be focused on a radio conversation between a new arrival and an elder. A medium term strategy would be to train local leaders to provide needed service, and an evaluation would be conducted through the implementing networks. Most of all, he stated that it was crucial to understand how natural counsel systems actually work.

Sociology

Dr. Jane Bertrand from Tulane University addressed various sociologic research approaches and their relative

utility for gathering quantitative or qualitative information required for designing effective interventions. By way of general guidance, Dr. Bertrand cautioned that there is no truly objective means of qualitatively or quantitatively measuring sexual behavior, and she recommended that populations be considered subunits (segments) to facilitate identifying obstacles to, and targeting messages for, behavior modification.

Survey research was cited as a tool well suited to yielding quantitative data, such as coital frequencies, but of limited use in determining motivations driving the behavior. Qualitative research techniques generally require long-term exposure to the study community, and information yield varies proportionately to labor intensity. Focus groups of eight to twelve subjects (people) are useful for determining community norms and sanctioned behavior, but seldom yield personal accounts of deviation from the norms or quantifiable data. Prospective diaries, generally assigned on a 24-hour basis for one-month periods, are difficult to implement, especially in developing countries. Individual interviews are the best means of uncovering motivations behind specific behaviors.

In the Africana situation, Dr. Bertrand suggested a combination approach of large-scale surveys utilizing oral questioning and recorded responses. For best results, survey results should be linked to scroprevalence data and the reliability of self-reported behavior should be tested through partner verification or test-retest studies.

Geography

Dr. George Demko from the Rockefeller Center, Dartmouth, gave a geographer's perspective on ways to meet the AIDS challenge. He explained that spatial networks, consisting of a probability field of contagion and (the spatial) diffusion of infection between locations, could be created to target transmission linkages among and within subregions.

Five major data sets would be needed: demographic data (including population distribution, ethnicity, migration patterns and age structure), transport systems (including migration and freight flows), medical systems (including mobile units and family planning clinics that are identified by magnitude and the areas they serve), morbidity and mortality rates, and any other reliable AIDS data.

Through a system of imagery four things could be accomplished:

- identify high density interaction points and spatial flow areas as prime locations for intervention;
- identify spatial correlations wit' those areas of high impact or high infection rates;

- · identify data deficient areas; and
- identify and monitor external connections to the area of study.

Dr. Demko acknowledged that data from developing countries are often difficult to find in the quantities needed for the Geographic Information Systems (GIS), but he was encouraged by the number of developing countries that had begun to employ them.

Policy Analysis

Dr. Rodger Yeager, from the University of West Virginia, presented policy considerations for behavioral intervention programs. He identified five discrete phases of exploration in the policy process: agenda-setting, formulation, adoption, implementation, and evaluation. In formulating policy interventions for the "Africana" case, one must take into consideration: a) organizational and logistic variables; b) hierarchical stratification and ethnic competition; c) demographically-distinct target groups; d) variable economic and political vulnerability; e) mistrust of foreign researchers and service organizations; and f) the total exclusion of women in the policy process.

Dr. Yeager recommended a number of policy actions which could be used in conjunction with medical and other behavioral interventions: encourage elites to articulate HIV/AIDS problems from their own points of view, particularly in the context of political stabilization and economic development, and ask them to look at past successes to uncover clues that can be applied to the AIDS situation; emphasize education programs in the long-term research and planning areas that are targeted for sexually immature populations, employ indigenous information gathering, policy making and administrative evaluative mechanisms in all program activities; avoid defining organizational to , tisses in terms of singular, highly visible crisis management, allow policy elites to legitimize program componer is and define minimal assistance needs regarding tinance, technology, infrastructure transfer, training and statting, encourage elites to employ NGOs, but accept those they find most useful; and encourage the incorporation of program funding into recurrent budgets of existing agencies, avoiding any funding as an add-on responsibility of foreign aid.

In sum, he urged program planners to convert the power relations in a controversial area of public policy to an opportunity to create a structure for problem solving relations. Dr. Yeager noticed that policy interventions in the context of AIDS are often rejected or ignored in many countries.

A Legislative Response from the U.S. Congress

Mr. Mark Kirk, former Chief of Staff for the Honorable John Porter (IL), outlined the history of U.S. funding for international AIDS, present conditions and possible future implications for funding.

Although funding for this area has steadily increased over past years, this trend may be reversed as the sense of international crisis abates relative to national priorities. Legislators respond to specific areas of concern, such as female circumcision, which are frequently brought to their attention by constituents and NGO's. The currently small base of Congressional support for international AIDS activities could be enhanced by engaging U.S.-based NGOs as constituent advocates, raising visibility in the media, and educating Congressional staffers.

Mr. Kirk advised that Congress is anxious to see results on the U.S. contribution of over \$200 million since the program's inception, and would prefer to see evidence of direct interventions, than to hear about operational research studies. He estimates that most legislators will be satisfied with approximately one more year of anecdotal impact reports and emotional stories, but believes through most of the '90s, Congress will look for a mass survey phase in the international AIDS strategy that will more concretely assess the impact of AIDS intervention and research programs.

PART III: SUMMARY PROCEEDINGS

Common Findings and Perspectives:

- More than one person has to be trained in AIDS behavioral intervention for program sustainability.
- Successful programs appear to be those that are integrated into ongoing health care systems.
- More research is needed on relapse behavior and the sustainability of behavior change.
- AIDS research should be anchored in other research traditions.
- The processes for decision-making for condom use are probably the same as those for family planning and other STD prevention.
- The key motivators for behavior change sprang from perceptions of social norms and peer acceptance.
- Institution-strengthening and capacity-building were integrated into many of the intervention programs discussed.

Agency for International Development (AID)

Dr. Susan Hassig from AIDSTECH and Dr. Susan Middlestadt from AIDSCOM presented summaries of AID's major behavioral intervention programs.

AIDSTECH: Dr. Hassig described three approaches used by AIDSTECH for behavioral intervention. The first targets interventions in diverse groups ranging from commercial sex workers to adolescents. The emphasis is on social marketing for condoms and STD control. Educational programs are developed for the target population, but often focus on other issues in addition to sexual transmission. The second approach is based on peer approaches and training which are central to community strategies. The third approach is clinic based, and a triangulation of approaches seemed to be the most effective. Again, as stated in the previous presentation by Dr. Liskin, the evaluators found that more that one person had to be trained for intervention implementation to maintain sustainability of the program. A 90% increase in attendance at STD clinics and 100% reported increase in condom use for 75% of the target population has occurred as a result of the programs.

AIDSCOM: Dr. Middlestadt talked about the external or structural targets and the internal, cognitive processes that can be used in intervention design. The internal variables include knowledge, severity, risk, attitudes toward behaviors, perceived consequences, perceived norms and self efficacy. AIDSCOM is running programs in 50 countries, with a focus on 12 emphasis countries. Dr. Middiestadt gave three examples of AIDSCOM programs located in different regions, focusing on inter-personal, mass media and community strategies. The inter-personal intervention, a condom skills training in the Latin American and Caribbean region, attempted to find reasons for condom use, instead of aiming for simple increased usage. She cautioned that inter-personal demonstrations and counselling sessions are very expensive. In addition, a comic book was designed to provide women arguments for negotiating condom use by her partner. The community wide intervention, a peer education project in Uganda, is based on the premise that changes in social norms can be produced by increased discussion of a given issue; changes in norms will produce changes in behavior, in this case condom use--"more talking, more norms leading to more condom use." Finally, she presented a mass media intervention, a national information campaign based on 30-60 second spots broadcasted in metropolitan Manila. These spots were effective in communicating information, as measured by the resulting increase in the use of an AIDS hotline advertised in the broadcasts. The aim of the program is to move beyond demonstrated change in beliefs to actual change in behavior. Dr. Middlestadt reminded the audience that the best interventions are wasted if condoms are not accessible.

United Nations Development Programme (UNDP)

Dr. Regina McNamara reported on the evolving policies of the UNDP, especially the program response to the epidemic's relationship with the status of women. Multidisciplinary and multi-sectoral approaches are focused on the local community, particularly with respect to women's awareness of the implications of the epidemic's multiple consequences. Prevention and care programs including home-care and small group counselling have been the focus of U.N. volunteer development missions in Malawi, Rwanda, Zambia and Thailand. In response to increased demands from the field, UNDP has engaged in two joint efforts to develop a policies-andprogramming handbook, and a resource center that will collect and disseminate AIDS literature from developing countries (being done in conjunction with Columbia University).

Walter Reed Army Institute of Research (WRAIR)

Dr. Lydia Temoshok discussed the HIV behavioral research program based in the Military Medical Research Program for Applied Retrovirology Research (MMCAR), a consortium that includes the Army, Navy, Air Force, Department of Defense and the Henry M. Jackson Foundation (the civilian counterpart.) All of the programs have three main missions: exposure prevention among the uninfected, transmission prevention in those who are infected, and the prevention of progression consequences such as lower job performance. The military struggles with the misconception that it is safe to have sexual relations with a member of the military because of routine and widespread testing. A number of infected women are still expressing a desire to have children. However, the military is uniquely situated since it can identify individuals soon after they become HIV positive. An example of current concern is the rerouting of 7000 soldiers through Thailand on their way home from active duty in the Middle East, because of the 40% infection rate in the brothels of Pattya. Beyond the descriptive clinical level, MMCAR is using applied tools such as an interactive video entitled "Body Armor."

Alcohol, Drug Abuse and Mental Health Administration (ADAMHA)

Dr. Ellen Stover highlighted a project in Brazil and one in Rwanda as examples of the 21 behavioral intervention projects that ADAMHA has funded for the past eight years. The study in Rwanda is providing preventive interventions to urban women of childbearing age, and is using an educational video in combination with small group discussions. Dr. Stover stressed that future interventions must also be targeted at men. The second inter-

vention is aimed at street children in Brazil and the city of Baltimore, utilizing media and small group skills training. A finding common for many organizations is that successful programs appear to be those that are integrated into ongoing systems of health care such as STD clinics or family medicine clinics. Dr. Stover stated the need to include researchers in intervention designs and noted the consistency of findings among all the organizations. She called for more research on relapse behavior and sustainability of behavior change.

International Development Research Centre (IDRC)

Sexual health is the main research focus of the IDRC, Ms. Pat Trites reported. The program emphasis is on integrating sexual health programs into existing projects instead of implementing vertical programs. IDRC is supporting 24 AIDS research programs at a total budget of 3,546,000 Canadian dollars. Thirty-three percent of the budget is obligated for counselling, education and social behavioral projects. Baseline data are being collected on people's knowledge, attitudes, beliefs and practices through surveys, in-depth interviews and focused group discussions. Ms. Trites gave two examples of programs in Uganda and the Dominican Republic. In Uganda, the radio seemed to be the primary source of AIDS information for most people. Subsequent to the radio campaign, an improvement in awareness levels resulted in reduced contact with prostitutes. Also, fewer sexual partners have been reported since the beginning of pilot studies begun in 1987. In the Dominican Republic, the intervention is targeted to very sexually active heterosexual young men who cater to tourists from North America and Europe. The distressing finding in this project was that condom use was consistent with first contacts, but as soon as a feeling of mutual trust was established, condom use ceased. This could occur in as little as three days' time.

World Health Organization (WHO)

Dr. Nina Ferenic reported on the two-fold mission of the WHO in the area of AIDS prevention and control. The first is to provide global leadership and guidance to national AIDS programs, and the second is the coordination of international efforts that combat AIDS. The program approaches are categorized by the target populations of the projects and the classifications include: safe sex promotion, condom promotion and distribution, education and skills training including training in negotiation, condom use skills, STD treatment and diagnostics, in addition to HIV testing and counselling. Behavioral research occurs in the context of establishing situations and networks among target audiences. All programs are based on an assessment of the existing structure and past experiences of the locality in order to determine study needs that can be used in the intervention design.

Pilot projects and evaluation of current and past programs are emphasized. KABP studies have been supported in over 70 countries and the findings have often been used to gain official government attention on the AIDS epidemic.

National Institutes of Health (NIH)

NIH programs were presented by Dr. Wendy Baldwin from the National Institute of Child Health and Human Development (NICHHD), Ms. Amy Scheon from the National Institute of Allergy and Infectious Disease, (NI-AID) and Dr. Sharlene Weiss from the National Center for Nursing Research (NCNR).

NICHHD: Echoing the views of other organizations, Dr. Baldwin said that NICHHD believes that AIDS research should be anchored in other research traditions. She also stated that although AIDS was obviously more serious than other STDs or pregnancy, the processes for decision making in the use of condoms were probably the same. In spite of the pressing need to implement interventions immediately, she cautioned against designing programs without the proper research. She encouraged collaboration on programs, if only because the AIDS challenge is enormous. The most recent grant applications received focused on the risk of STDs and AIDS, and on behavioral research on sexual decision making and contraceptive practice, especially condoms. The NIH mandate allows for international research that addresses the basic theoretical questions, and Dr. Baldwin felt that a demography of sexual behavior was particularly needed.

NIAID: Ms. Scheon reported that the NIAID studies are aimed at reducing the infectiousness of the disease in order to reduce the probability that infection will occur after exposure. NIAID researchers are also trying to quantify risk behaviors and the prevalence of those behaviors in selected societies. Ms. Scheon felt that the opportunity for integration of behavioral intervention studies with the epidemiologic infrastructure or with vaccine trials was vastly underexploited. She stated that evaluation of the impact of interventions and controlled studies to compare the efficacies of different interventions would provide information on what actually works. As an example, cohort studies provide the perfect opportunity to study behaviors since the behaviors are quantified and the laboratory and clinical infrastructures are in place. Several more examples were presented, ranging from perinatal transmission studies and HIV-2 studies to investigation on diarrhea and wasting. She called for evaluation that extends beyond selfreported behavior to the effects of counselling and condom promotion.

NCNR: Dr. Weiss presented a large collaborative effort between USAID through AIDSTECH and NIH through the National Center for Nursing Research and the Fogarty Center. The two objectives of this effort are to provide information on high risk behaviors, behavior change, and institution strengthening that would leave developing countries with the ability to conduct behavioral research. The studies identify behaviors most amenable to change, sometimes through an intervention, and have two phases. The first phase assesses feasibility after one year, and after a subsequent three-year implementation pending the outcome of the review. Nine studies have been selected for phase one in Uganda, Bostwana, Zimbabwe, Thailand, Indonesia, Mexico, Haiti, Jamaica and Chile. The health belief model is being tested in Haiti, Indonesia and Uganda. The first phase findings show that simple models do not explain complex behavior. Fishbein's theory of reasoned action is being tested in Zimbabwe. The AIDS risk reduction model is being tested in Thailand and Chile. The social influence model is being examined in Mexico, and several peer education approaches are being tried in Botswana. Factors related to decision making as model testing are being studied in Jamaica. The programs are aimed at a wide variety of study populations, and the individual programs are not in competition with each other. Dr. Weiss stressed the need to explain how research can lead to intervention. The first phase of the program was funded by USAID at a cost of \$800,000. If all nine projects are funded in the second phase, NIH will support four of them, and the remaining five will be supported by USAID.

Centers for Disease Control (CDC)

Dr. Melinda Moore drew parallels between the structure of the CDC's domestic interventions and international applications. She explained that HIV is matrix managed within the agency, since HIV related activities are integrated into all of the major organizational components of the CDC. Formative research evaluating condom-related messages and the possible links between family planning and HIV/STD control is underway. A collaboration that is evaluating behavioral indicators related to HIV and STD is being conducted with AID through AIDSTECH/AIDSCOM. A possible future program, again in collaboration with AID, would create HIV/STD prevention laboratory centers. The centers would conduct research and provide training, and

through multidisciplinary efforts would work with a mandate to operationalize research findings into programs. International HIV community demonstration projects have a budget of approximately six million dollars. The first phase of these projects include developmental research which begins with an ethnographic study of geographic areas where the prevalence of risk-taking behaviors is high. The second phase uses role model stories, small media, and peer networks to distribute educational materials, referrals to services, and risk-reduction materials. A common finding of the CDC-sponsored programs was that the key motivators to behavior change sprang from perceptions of social norms and peer acceptance.

Rockefeller Foundation

Dr. Seth Berkley warned that many of the STDs in the developing world are very difficult to diagnosis, which therefore impeded the ability to create interventions. He reported on an STD diagnostics network comprised of multiple donors that is looking at ways to develop laboratory tests or use already developed tests in inexpensive ways to make them accessible, stable at room temperature, and simple to use. He told participants about plans among the international bilaterals to develop a program with indigenous Non-Governmental Organizations (NGOs) to provide them with technical and financial support, in addition to creating a network for them. A component of Rockefeller's INCLEN program trains social scientists in 27 program units in 16 countries. A meeting planned for August will focus on training people to undertake formative and operational behavioral research. As an offshoot of this initiative, collaborative plans are underway to develop an international social science forum.



The International Forum for AIDS Research is located within the Division of International Health, Institute of Medicine, National Academy of Sciences.

2101 Constitution Avenue, N.W. Washington, DC 20418 Tel: (202) 334-3613 Fax: (202) 334-3861

Direct Inquiries to:

Christopher P. Howson, PhD, Director Lita Curtis, MPH, Associate Director



International Forum for AIDS Research

Institute of Medicine National Academy of Sciences

International HIV/AIDS Research Priorities

The sixth and final meeting of

IFAR at the Institute of Med-

icine was held on 11 March

1992 to review the forum's

mandate in light of the chang-

ing nature of, and program re-

sponses to, the HIV/AIDS

pandemic.

The International Forum for AIDS Research (IFAR) was established at the Institute of Medicine of the National Academy of Sciences in January 1990 to enhance coordination of research activities aimed at prevention and control of HIV/AIDS. The founding membership of IFAR included North American funders and the World Health Organization. IFAR is in its third and final year of sponsorship at the Institute of Medicine, and this infold reports on its fifth and sixth meetings, its final two at the Institute of Medicine. The fifth meeting, held on 14–15 November 1991, provided for review of the international HIV/AIDS-related research priorities and program activities of member organizations. The sixth and final meeting of IFAR at the Institute of Medicine was held on 11 March 1992 to review the forum's mandate in

light of the changing nature of, and program responses to, the HIV/AIDS pandemic and to elicit discussion on how the structure and activities of a future IFAR should usefully evolve in response.

The initial concept for the Forum emerged from a series of meetings in 1988-89 among administrators and research scientists concerned with the problems raised by the AIDS pandemic in developing countries. The consensus of meeting participants was that there was a need to increase information ex-

change among funding agencies in order to highlight gaps in knowledge for the purposes of informing future research, and to review, on an ongoing basis, the range and types of international HIV/AIDS-related research and intervention programs. The goal of this information exchange would be to help member organizations to identify gaps, productive and nonproductive duplications, and complementarities in their research, intervention, and training activities.

The charge to IFAR was to:

 Create and maintain a network of institutional linkages and information exchange among concerned funding agencies and interested governments; •Foster sustained dialogue aimed at guiding the international applied research agenda toward greater coherence, complementarity, and productivity;

•Marshall support for high-priority collaborative activities, including long-term institution-building efforts and multidisciplinary efforts.

The first meeting of IFAR sought to clarify individual member's organizational objectives and mandates. The next three meetings focused on specific topics of interest to members. The second meeting focused on capacity building and covered such topics as where, whom, and how to train; what support structures must be contemplated; and how training investments could be best monitored and protected (see AIDS & Society, vol.2, no.1). The third meeting discussed the preparatory steps

necessary towards successful management of international vaccine trials. Among the issues considered were the current status of promising candidate vaccines; ethical and legal aspects of Phase II and III trials in the developing world; and potential obstacles related to implementation of these trials (see AIDS & Society, vol. 2, no. 2).

The fourth meeting considered behavioral interventions for the prevention of sexual transmission of

HIV. This meeting was organized around three overall objectives: 1) to consider a model for categorizing behavioral interventions; 2) to share information about current behavioral intervention programs in which IFAR members were involved; and 3) to foster discussion about the adequacy of present strategies (see AIDS & Society, vol 2, no. 4).

The fifth IFAR meeting was designed to move away from the technical exchange of information, which had been the core of the previous three meetings, toward a more interactive session where members as a group could share information about their respective organization's major program priorities and current activities re-

lated to international HIV/AIDS research, intervention, and training. The goal of this meeting, the first of its kind among international funders of HIV/AIDS program activities, was to determine the degree to which the major HIV/AIDS research, intervention, and training activities of member agencies reflect current priorities as identified by IFAR members. The meeting also marked the expansion of IFAR membership to include international funders in Europe. Mr. Pierre LaCroix, of the International Development Research Centre of Canada, acted as meeting facilitator.

Advance Preparation

To facilitate discussion of research priorities, IFAR members were asked, in advance of the meeting, to answer the following three questions.

From your organization's perspective, what are:

- The three most important current HIV/AIDS issues (e.g. partner reduction, political will, socioeconomic impact of the epidemic)?
- •The three to five most important current HIV/AIDS research priorities (e.g. vaccine development, condom utilization)?
- •The two most important gaps in HIV/AIDS research (e.g. diagnostics, role of cofactors such as STDs in HIV transmission and disease progression)?

In identifying the research priorities in Question 2, IFAR members were asked that these reflect the "80-20 law" -- i.e., the top-priority areas listed should account for 80 percent of the member organization's international HIV/AIDS research budget.

Responses to Question 1 -- Major Issues

Approximately 50 key issues were identified by IFAR members prior to the meeting. At the meeting itself, these issues were then grouped by the participants into nine general categories:

- •Vaccine Development and Other Biomedical Research;
 - Behavioral Research and Interventions;
- Support for Community Methods of Prevention and Care:
- •Treatment and Research of Sexually–Transmitted Infections and Diseases (SHs and STDs);
 - •Capacity Building and Infrastructure Strengthening;
- •Government Commitment and Political Will for a Rational HIV/AIDS Policy;
 - Surveillance and Monitoring;
- Identification and Setting of Priorities Among Funded Activities; and
- Media Messages and Public Response to the Pandemic.

Responses to Question 2 -- Research Priorities

Over 30 research priorities were identified by IFAR members before and during the meeting. These were

then grouped into the following three general priority areas:

- •Prevention of HIV Transmission: Interventions and programs that will either result in the development of a vaccine, change the behaviors that facilitate transmission, or diagnose and treat related STDs:
- •Provision of care for HIV-infected persons and their survivors: Medical treatments and behavioral strategies that help infected persons and their survivors (who are frequently their caregivers) to cope with the disease;
- •Assessing and providing mechanisms for coping with the socioeconomic impact of HIV/AIDS: Geopolitical, societal, cultural, and economic implications of the burden of the disease, and best possible methods for mitigating the impact.

Responses to Question 3 -- Research Gaps

Approximately 40 research gaps were identified by IFAR members. These were grouped into the following two broad categories:

- •Biomedical and vaccine research. Gaps identified in this category included: applied diagnostics, vaccine development; universal accessibility of vaccines; lack of laboratory correlates of HIV immunity; assessment of capability at proposed study sites; biological, clinical, and virologic research; better understanding of the natural history of HIV (including appropriate markers of disease progression and immunity); improved diagnostics for pediatric HIV infection; simpler and inexpensive diagnostic tests for treatable STDs; female-controlled barrier methods for preventing STIs; and research on the extent to which cofactors, HIV variation, and cultural determinants may influence host response to HIV vaccine candidates.
- •Behavior change research and intervention. Gaps identified for this category included: gender-targeted approaches to behavior change; societal constraints on gender-targeted approaches; the lack of insights and perspectives in the literature from those most affected by the pandemic; socioeconomic differentiation in HIV transmission; and accessibility of research findings to advocates, infected persons, and their survivors.

Future Directions for IFAR

As one of the final topics of the November meeting, members discussed whether IFAR had fulfilled its mandate as a forum for information exchange and networking in a neutral setting. Members also considered whether IFAR should continue once its term at the Institute of Medicine was completed in mid-1992. Members agreed that a subcommittee should be formed to examine the IFAR mandate to suggest whether the Forum's structure and activities should be amended to adjust to the changing characteristics of the HIV/AIDS pandemic in the 1990s.

The subcommittee met twice in late 1991 and subsequently presented its suggestions to the full IFAR

International Forum for AIDS Research Membership Roster

→ AGENCY FOR INTERNATIONAL DEVELOPMENT Bureau for Research and Development/Health AIDS Division Washington, DC 20523-1817 U. S. A.

Robert Bernstein Jeff Harris Julie Klement Bradshaw Langmaid William H. Lyerly, Jr.

Melody Trotť

→ AMERICAN FOUNDATION FOR AIDS RESEARCH 733 Third Avenue 12th Floor New York, NY 10017 U. S. A.

Vivia Dennis

Mervyn F. Silverman

Margaret Reinfeld

☐ CENTERS FOR DISEASE CONTROL Division of HIV/AIDS -- International Activity Atlanta, GA 30333 U. S. A.

Helene Gavle

→ FORD FOUNDATION 320 East 43rd Street New York, NY 10017 U. S. A.

Jose Barzelatto Christina Cuevas

→ GERMAN AGENCY FOR TECHNICAL DEVELOPMENT Division of Health, Population, Development, and Nutrition D-6236 Eschborn Postfach 5180 Dag-Hammarskjold-Weg 1-2 Frankfurt/Main, Germany

Thomas Rehle

→ INTERNATIONAL DEVELOPMENT RESEARCH CENTRE Health Sciences Division P. O. Box 8500 Ottawa, Ontario Canada K1G 3H9

Don de Savigny Karl Smith **Pat Trites**

→ NIH - FOGARTY INTERNATIONAL CENTER Building 38A 9000 Rockville Pike Bethesda, MD 20892 U. S. A.

Kenneth Bridbord Alastair Clayton Phillip Schambra

☐ NIH - NATIONAL INSTITUTE FOR ALLERGY AND INFECTIOUS DISEASES (NIAID)
Solar Building, Room 3C-2S

Bethesda, MD 20892 U.S.A.

Karl A. Western

→ NIH - NIAID, DIVISION OF AIDS 6003 Executive Boulevard Rockville, MD 20852 U. S. A.

Robert Fischer Dan Hoth Dale Lawrence Beth Ungar

→ NIH - OFFICE OF AIDS RESEARCH Building 1, Room 201 Bethesda, MD 20892 U. S. A.

Linda Reck Jack Whitescarver

☐ PAN AMERICAN HEALTH ORGANIZATION 525 23rd Street, N. W. Washington, DC 20037 U. S. A.

A. David Brandling-Bennet Mercedes Weissenbacher

→ ROCKEFELLER FOUNDATION 1133 Avenue of the Americas New York, NY 10036 U. S. A.

Seth Berkley

→ UNITED NATIONS DEVELOPMENT PROGRAMME Division for Global and Interregional Programmes One United Nations Plaza New York, NY 10017 U. S. A.

Elizabeth Reid Timothy S. Rothermel

IFAR Membership Roster

(from page 3)

☐ U.S. PUBLIC HEALTH SERVICE Medical and Scientific Affairs Office of International Health Department of Health and Human Services 18-87 Parklawn Building 5600 Fishers Lane Rockville, MD 20857 U. S. A.

Kenneth Bernard

→ U. S. PUBLIC HEALTH SERVICE National AIDS Program Office Office of the Assistant Secretary for Health 200 Independence Avenue Room 738-G, HHH Building Washington, DC 20201 U. S. A.

Valerie Setlow

☐ WALTER REED ARMY INSTITUTE OF RESEARCH Division of Retrovirology Walter Reed Army Institute of Research 13 Taft Court, Suite 201 Rockville, MD 20850 U. S. A.

Donald Burke

☐ WORLD BANK
Division of Population, Health, and Nutrition
1818 H Street, N. W.
Washington, DC 20433 U. S. A.

Randy Bulatao Mead Over Wendy Roseberry

☐ WORLD HEALTH ORGANIZATION Global Programme on AIDS 1211 Geneva 27 SWITZERLAND

David Heymann Michael Merson

International Forum for AIDS Research Staff:

Christopher P. Howson, Ph.D, IFAR Director and Deputy Director, Division of International Health

Dana Hotra, MHS, IFAR Deputy Director

Polly F. Harrison, Ph.D, Director, Division of International Health

> Sharon Scott-Brown, Administrative Secretary, Division of International Health

Research Priorities

(from page 2)

membership at its March meeting. At this meeting, members were asked to address the following four interrelated questions:

- 1) Should IFAR continue in any form?
- 2) Should IFAR's membership include only North American-based funders, or should it include funders from other regions of the world as well?
- 3) Should IFAR serve solely as a means for conveying funders of international HIV/AIDS research, or should it adopt a more proactive role, for example, by encouraging increased dialogue between funders and developing world recipients of those funds?
 - 4) Where should IFAR be located?

Members agreed that IFAR should continue in some form. The International Development Research Centre of Canada indicated interest in hosting IFAR, provided that the Forum were to be truly international in membership and actively informed by a wider community of international HIV/AIDS experts, for example, regional and local recipients of funding. The Global Programme on AIDS of the World Health Organization also expressed interest in hosting IFAR. It was suggested that the Programme could convene funders on at least an annual basis to review their international HIV/AIDSrelated research and intervention programs. Members indicated support for both proposals and agreed that the International Development Research Centre should explore potential funder interest in participating in a revised forum.



The International Forum for AIDS Research is located within the Division of International Health, Institute of Medicine, National Academy of Sciences.

2101 Constitution Avenue, N.W. Washington, D.C. 20418 Tel: (202) 334-2348 Fax: (202) 334-3861

Direct inquiries to: Dana Hotra, MHS, Deputy Director